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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	4538US
First Inventor or Application Identifier	Paul C. Daly
Title	SYSTEM, METHOD AND PACKAGE FOR PROVIDING A SUCROSE SOLUTION
Express Mail Label No.	EL700253825US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231

jc675 U.S. PTO 09/670781 09/27/00

1. [ ] * Fee Transmittal Form *(e.g., PTO/SB/17)* *(Submit an original, and a duplicate for fee processing)*
2. [X] Specification [Total Pages 10] *(preferred arrangement set forth below)*
   - Descriptive title of the Invention
   - Cross References to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to Microfiche Appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
3. [X] Drawing(s) *(35 U.S.C. 113)* [Total Sheets 2]
4. Oath or Declaration [Total Pages]
   a. [ ] Newly executed (original or copy)
   b. [ ] Copy from a prior application (37 C.F.R. § 1.63(d)) *(for continuation/divisional with Box 17 completed)* ***[Note Box 5 below]***
      i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).
5. [ ] Incorporation By Reference *(useable if Box 4b is checked)* The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered to be part of the disclosure of the accompanying application and is hereby incorporated by reference therein.
6. [ ] Microfiche Computer Program *(Appendix)*
7. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   a. [ ] Computer Readable Copy
   b. [ ] Paper Copy (identical to computer copy)
   c. [ ] Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

8. [ ] Assignment Papers (cover sheet & document(s))
9. [ ] 37 C.F.R.§3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
10. [ ] English Translation Document *(if applicable)*
11. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
12. [ ] Preliminary Amendment
13. [X] Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
14. [ ] * Small Entity Statement(s) *(PTO/SB/09-12)* [ ] Statement filed in prior application, Status still proper and desired
15. [ ] Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
16. [X] Other: Unexecuted Copy of Declaration

** A new statement is required to be entitled to pay small entity fees, except where one has been filed in a prior application and is being relied upon.*

17. **If a CONTINUING APPLICATION,** *check appropriate box, and supply the requisite information below and in a preliminary amendment:*
    [ ] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No: _____/_____
    Prior application information: Examiner _____ Group / Art Unit: _____

18. CORRESPONDENCE ADDRESS

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Signature		Date	09/27/00

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PATENT
Attorney Docket 4538US

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APPLICATION FOR LETTERS PATENT

for

SYSTEM, METHOD AND PACKAGE FOR PROVIDING A SUCROSE SOLUTION

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SYSTEM, METHOD AND PACKAGE FOR PROVIDING A SUCROSE SOLUTION

BACKGROUND OF THE INVENTION

Field of the Invention: The present invention relates to providing a sucrose solution having demonstrated analgesic and calming effects for use with neonatal infants and, more specifically, a system, method and package for providing such solutions in prepackaged, sterile form.

State of the Art: All newborn infants are subjected to a variety of medical procedures after birth. Such procedures include, by way of example only, vitamin K injections, immunization, circumcision, and venipuncture or heel stick for blood sampling. Preterm or ill infants experience additional, often painful and stressful, diagnostic procedures and treatments. However, only in rare instances do neonatal infants receive prophylactic analgesia.

Neonatal infants demonstrate a preference for sweet tasting substances, including sucrose, fructose and glucose as well as artificial sweeteners. Intake of sucrose has demonstrated analgesic and calming effects on infants, and the other substances previously mentioned may have similar effects, but this has not been proven. On the other hand, lactose apparently does not induce analgesia or calming effects in newborn infants. Moreover, administration of oral sucrose has been proven to promote increased sucking and hand-to-mouth behavior in infants as well as reducing crying-related energy expenditure, the absence of which may positively affect feeding behavior and growth. No published studies of the analgesic or calming effect of dextrose are known to the inventor.

Current practice in hospitals employing substances such as sucrose, dextrose or even common table sugar is to mix up a large batch of solution in an on-site kitchen or pharmacy. As noted above, sucrose is the only sugar recognized uniformly to provide the desired analgesic and calming effects so, in some instances, administration of a sweet solution to infants is not efficacious. Moreover, the conditions in which these sweet solutions are mixed on site are by no means sterile, and the human traffic in the preparation environment increases an already substantial risk of contamination. Cross

contamination between patients is also a problem, as doses of solution may be given to more than one patient from the same container.

Finally, even when sucrose is conventionally employed, formulations of the sweet solutions are not carefully controlled and, therefore, the desired results not always or even predictably achieved. Studies have indicated that the minimum concentration of sucrose needed to produce effective analgesia for procedural pain may be about 18%. Although such studies are not definitive, it has been established that too low a concentration of sucrose may not be efficacious. On the other hand, overly high dosages of sugars to infants are known to be detrimental.

It would thus be desirable to provide a technique for preparation and administration of sucrose solutions by clinicians in an effective manner and without the deficiencies attendant to conventional procedures.

BRIEF SUMMARY OF THE INVENTION

The present invention comprises a system, method and package for providing sucrose solutions to neonatal infants.

According to the present invention, a solution of sucrose and water is formulated with a percentage of about 10% to about 50% sucrose, the remainder of the solution comprising water. The solution is metered into a cup or other container for single patient use or dosage. The product is packed aseptically or post-process sterilized for safety and freshness, and leaves the preparation site in a sealed, sterile state. Multiple containers of packaged solution are boxed and shipped to the end user. At the site of usage, a container is opened and the solution administered prior to a painful or otherwise stressful procedure, for example by dipping a pacifier in the opened container or drawing a small volume of solution into a dropper or syringe, the solution then be administered orally.

Other features and advantages of the present invention will become apparent to those of skill in the art through a consideration of the ensuing description, the accompanying drawings, and the appended claims.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

In the drawings, which illustrate what is currently considered to be the best mode for carrying out the invention:

FIG. 1 is a side sectional elevation of a cup-like container holding a volume of analgesic solution according to the present invention;

FIG. 2 is a partially cut away perspective view of a plurality of the cup-like containers of FIG. 1 holding solution; and

FIG. 3 is a flow diagram of a method of preparing and administering the analgesic solution according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to FIG.1 of the drawings, a thermally-formed or injection-molded polymer container 10 in a cup shape defining a cavity 12 and having a peripheral flange 14 at the mouth 16 thereof is filled, by way of example only, with about 40 ml of solution 18. After introduction of solution 18 into cavity 12, a cover 20 of a polymer film, a metal foil, a metallized insulating film or other suitable material is applied over mouth 16 and sealed to peripheral flange 14 by techniques known in the art. Peripheral flange 14 may have an annular indentation or groove in the top surface thereof as shown in broken lines 14a to facilitate cover 20 being sealed to peripheral flange 14 therealong by, for example, point contact with a heating tool. Cover 20 extends at least to an outer edge of peripheral flange 14. Container 10 as shown (see FIG. 2) is round, but other configurations such as square or rectangular with a like-shaped cover are contemplated. Suitable labeling (not shown) may be applied to the top of cover 20, as desired, for ease of viewing by the user.

Solution 18 may comprise a sucrose and water solution in the range of about 10% to about 50% sucrose, the remainder of the solution comprising water. The sucrose may be USP grade or clean sucrose, and the water clean or sterile. It is preferred currently by the inventor that solution 18 comprise about 24% USP grade liquid sucrose to about 76% clean water.

As noted above, the formulation and packaging of solution 18 may be performed aseptically or sterilization may be effected as a post process operation. Gamma

irradiation is contemplated as one suitable post process sterilization technique. The manner of preparing and packaging analgesic solution 18 according to the invention is known to those of ordinary skill in the relevant art, and so no further explanation thereof is deemed necessary.

FIG. 2 shows a plurality of sealed, cup-like containers 10 disposed in a box 30 for shipping. In the example shown, five groups of ten containers 10 each are layered in box 30 with spacer sheets 32 disposed between each layer, under the bottom layer and over the top layer. It may also be more easily seen from FIG. 2 that covers 20 of containers 10 includes integral protrusions or tabs 22 extending substantially beyond the outer extent of peripheral flanges 14 at one side thereof, the remaining periphery of covers 20 substantially following the outer extent of flanges 14. If desired, flanges 14 may also include a tab or protrusion 14b of similar shape to protrusion or tab 22 as shown in broken lines in FIG. 1 to protect protrusion 22 from inadvertent lifting during handling and shipping. Protrusion 22 enables gripping by the user to facilitate peeling the cover 20 off of container 10 for access to solution 18 in cavity through the wide mouth 16 as shown in broken lines. The relatively shallow depth and wide mouth configuration of container 10 is particularly advantageous for dipping of a pacifier end therein to coat it with solution 18 prior to insertion in an infant's mouth for the infant to suck. It may desirable to configure container 10 as even wider and shallower than as currently depicted in the drawings, to prevent tipping thereof if a pacifier is left therein between dosings. Similarly, the exemplary 40 ml volume of solution 18 in internal chamber 12 may be reduced to a lesser volume, for example 20 ml, as desired.

In accordance with the invention, it is preferred that a dose of no more than about 2 ml of solution 18 be administered to an infant for analgesia, approximately two minutes prior to a planned procedure. If a pacifier is employed, it may be dipped in analgesic solution 18 and inserted in the infant's mouth. In such an instance, a dose of solution 18 may comprise about 0.2 ml. Recoating of the pacifier should only be effected as needed, not to exceed administration of the aforementioned 2 ml of solution 18. If administered by syringe or dropper, a few drops of solution 18 may be applied to the tongue or buccal surface. A dose volume of 0.05 to 2 ml is preferred. Repeat doses of solution 18, which

may be administered during and immediately following the procedure, should not exceed the aforementioned 2 ml total volume. After the procedure, container 10 with residual solution 18 should be discarded to avoid any potential for cross contamination of other infants.

FIG. 3 comprises a flow diagram of an exemplary method of carrying out the present invention, comprising preparing the solution 18, packaging solution 18 in containers 10 either aseptically or with post process sterilization, boxing multiple containers 10 for shipment and shipping to a usage site (e.g., hospital), opening a container 10 in association with a planned procedure, administering the solution 18, and discarding any residual solution after the procedure. Of course, it would be possible to practice the invention by preparing solution 18 on site, packaging it aseptically and then using it on site. However, most if not all hospitals are equipped to perform a packaging operation as contemplated by the invention.

While the present invention has been described with respect to an illustrated embodiment, those of ordinary skill in the art will understand and appreciate that additions, deletions and modification to the illustrated embodiment are possible without departing from the scope of the invention as encompassed by the claims herein.

CLAIMS

What is claimed is:

1. A packaged solution, comprising:

a cup-shaped container defining a cavity therein opening to a mouth;

a volume of a solution comprising sucrose and water within the cavity; and

a cover disposed over the mouth of the container and sealing the solution within the cavity.

2. The packaged solution of claim 1, wherein the cover includes a lateral protrusion.

3. The packaged solution of claim 2, wherein the container includes a peripheral flange about the mouth, and the cover extends peripherally at least to an outer end of the flange.

4. The packaged solution of claim 3, wherein the peripheral flange includes a lateral protrusion and the lateral protrusion of the cover is substantially aligned therewith.

5. The packaged solution of claim 1, wherein the cover is sealed to the container.

6. The packaged solution of claim 5, wherein the container includes a peripheral flange about the mouth, and the cover extends peripherally at least to an outer end of the flange.

7. The packaged solution of claim 6, wherein the cover is sealed to the peripheral flange.

8. The packaged solution of claim 1, wherein the solution and an interior of the container are in an aseptic state.

9. The packaged solution of claim 1, wherein the solution comprises about 10% to about 50% sucrose with a remainder of the solution comprising water.

10. The packaged solution of claim 1, wherein the solution comprises about 24% USP grade liquid sucrose to about 76% clean water.

11. The packaged solution of claim 1, wherein the cup-shaped container has a greater width than depth.

12. A system for providing a solution for use in conjunction with a planned medical procedure on a neonatal infant, comprising:
preparing a solution comprising sucrose and water;
packaging the solution in single use containers;
assembling a plurality of single use containers in a shipping container;
shipping the container to an intended site of usage of the solution;
opening an individual, single use container of the solution prior to the planned procedure;
administering a selected volume dose of the solution orally to the neonatal infant; and
discarding any residual solution with the opened, individual, single use container after the procedure.

13. The system of claim 12, further comprising maintaining the solution in each single use container in an aseptic state after packaging until opening thereof for the planned medical procedure.

14. The system of claim 12, further comprising packaging the solution in cup-shaped single use containers having covers sealed over mouths thereof.

15. The system of claim 12, further comprising formulating the solution to comprise between about 10% and about 50% sucrose with a remainder of the solution comprising water.

16. The method of claim 12, further comprising formulating the solution to comprise about 24% USP grade liquid sucrose to 76% clean water.

17. A method of administering a solution to a neonatal infant, comprising:

providing a solution comprising sucrose and water in an aseptic state and in a volume selected for single patient use within a sealed container;

opening the container;

withdrawing a selected dose of solution from the opened container and administering the selected dose to the neonatal infant; and

discarding any residual solution with the container.

18. The method of claim 17, wherein the container is cup-shaped and the opening thereof comprises peeling off a cover sealed over a mouth of the container.

19. The method of claim 17, further comprising providing the solution as between about 10% and about 50% sucrose with a remainder of the solution comprising water.

20. The method of claim 17, further comprising providing the solution as about 24% USP grade liquid sucrose to about 76% clean water.

ABSTRACT OF THE DISCLOSURE

A solution of sucrose and water is packaged and placed in an aseptic state for single patient use in a cup-shaped container with a removable cover. A plurality of containers are shipped from a preparation site to a site of usage such as a hospital. A single container of the solution is opened at a site of a procedure for a neonatal infant, and the solution administered prior to the procedure as well as during or afterward, as needed for analgesic effect. Any residual solution is discarded after the procedure to prevent cross contamination of other patients.

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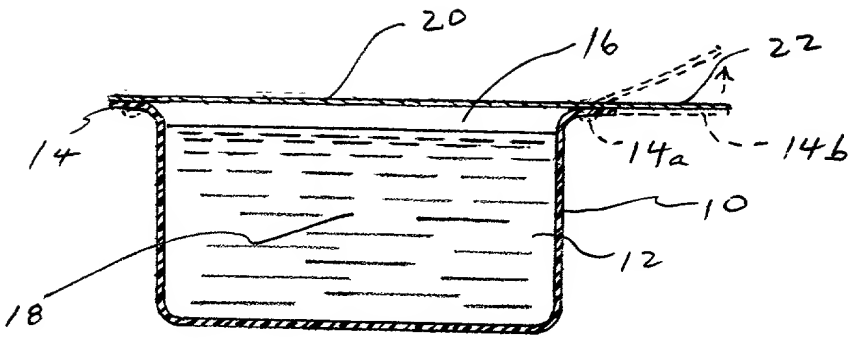

FIG. 1

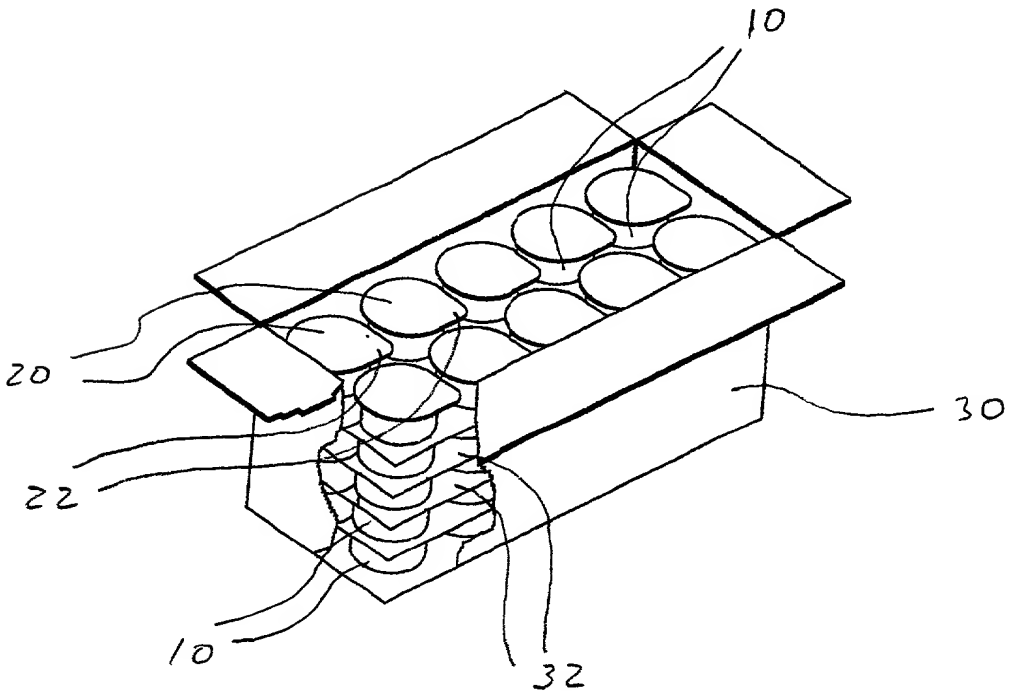

FIG. 2

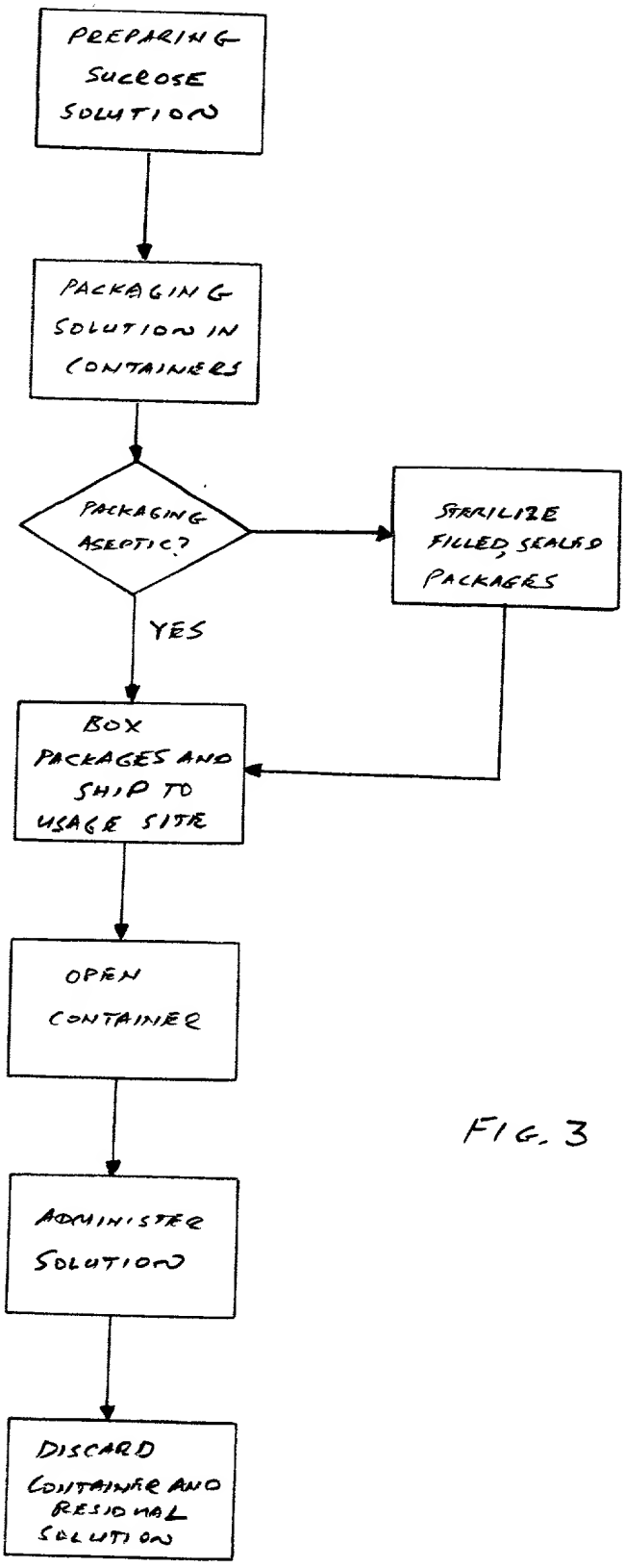
PREPARING SUCROSE SOLUTION
PACKAGING SOLUTION IN CONTAINERS
PACKAGING ASEPTIC?
YES
STERILIZE FILLED, SEALED PACKAGES
BOX PACKAGES AND SHIP TO USAGE SITE
OPEN CONTAINER
ADMINISTER SOLUTION
DISCARD CONTAINER AND RESIDUAL SOLUTION

FIG. 3

DECLARATION FOR PATENT APPLICATION (WITH POWER OF ATTORNEY)

As an inventor named below or on any attached continuation page, I hereby declare that:

My residence, post office address and citizenship are as stated next to my name.

I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled SYSTEM, METHOD AND PACKAGE FOR PROVIDING A SUCROSE SOLUTION, the specification of which (check one):

- ☒ is attached hereto.
- ☐ was filed on _____ as United States application serial no. _____ and was amended on _____.
- ☐ was filed on _____ as PCT international application no. _____ and was amended under PCT Article 19 on _____.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to me to be material to the patentability of the subject matter claimed in this application, as "materiality" is defined in Title 37, Code of Federal Regulations § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate or § 365(a) of any PCT international application(s) designating at least one country other than the United States of America listed below and on any attached continuation page and have also identified below and on any attached continuation page any foreign application for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America having a filing date before that of the application(s) on which priority is claimed.

Prior foreign/PCT application(s):

			Priority Claimed	
(number)	(country)	(day/month/year filed)	Yes	No
(number)	(country)	(day/month/year filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) or § 365(c) of PCT international application(s) designating the United States of America listed below and on any attached continuation page and, insofar as the subject matter of each of the claims of this application is not disclosed in any such prior application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations § 1.56 which became available between the filing date of such prior application and the national or PCT international filing date of this application:

(application serial no.)	(filing date)	(status - pending, patented or abandoned)
(application serial no.)	(filing date)	(status - pending, patented or abandoned)

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

(provisional application no.)	(filing date)

I hereby appoint the following Registered Practitioners to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Inventor's signature _____ Date _____
Residence: Abington, Massachusetts
Citizenship: U.S.A.
Post Office Address: 176 Chapel Street, Abington, Massachusetts